

Application No. 10/667,237
Amendment Dated December 11, 2006
Reply to Office Action of August 10, 2006

Amendments to the Drawings:

Attachment: Replacement Sheet

REMARKS

The Office Action mailed August 10, 2006 has been carefully considered by applicant. Reconsideration is respectfully requested in view of the foregoing amendments to the specification and claims, and the remarks that follow.

Drawings

The drawings are amended to overcome the objections set forth in the Office Action. More particularly, the reference number 25 is added to Figure 2 and the reference numbers 20 and 22 are added to Figure 4. No new matter is added by these amendments.

Specification

The disclosure is amended to overcome the objections set forth in the Office Action. More particularly, page 8, line 21 has been amended to refer to the display with reference number 24. As discussed above, the drawings are amended to overcome the remaining objections to the specification. No new matter is added by these amendments.

Claim Rejection

Claims 1, 2, 4-14 and 17-28 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Burton et al. International Publication No. 2002/100267. Claims 3, 15 and 16 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Burton et al. in view of Oliveria et al. U.S. Patent No. 5,002,151.

Claim 1

Claim 1 recites a unitary sensor for detecting biopotential signals on the skin of a patient. The unitary sensor includes a base strip and an integrally formed extension strip extending from the base strip to a distal end. The base strip includes at least three electrodes for detecting biopotential signals on the skin of a patient. The extension strip includes an acoustic emitter attached to the distal end.

Burton et al. discusses on page 78 and 79 an acoustic emitter earpiece that is optional and that may be connected to an electronics module of the system via a wired or wireless connection. Burton et al. do not teach or suggest the claimed acoustic emitter attached to the distal end of an extension strip that is integrally formed with the base strip. In fact, Burton et al. teaches against such an arrangement by discussing and depicting (see

Figs. 36 and 37) a lead wire attached to the electronic module. Burton et al. does not display any lead or wire between the electrode strip and the AEP ear module (which in Fig. 37 is actually labeled erroneously as mic module, instead of loud speaker). Fig. 37 also exhibits a wireless option as the preferred embodiment.

In view of the contrary teachings of Burton et al., claim 1 is clearly not anticipated, nor rendered obvious by the Burton et al. reference.

The shortcomings of Burton et al. are not overcome by Oliveria et al. '151.

Claims 2-7

Claims 2-7 depend directly or indirectly from claim 1 and are thus believed allowable for the reason stated above, as well as the detailed subject matter recited therein.

Claim 8

Claim 8 is amended to more particularly point out and distinctly claim the subject matter of the present invention and to render the same allowable over the applied references.

Claim 8 now recites that the control unit is operable to select between the active measurement module and the passive measurement module such that the control unit displays the current level of brain function from only one of the active measurement module such that the control unit displays the current level of brain function from only one of the active measurement module and passive measurement module at any given time. This aspect is neither taught nor suggested by Burton et al., which teaches a combined system. The control unit of Burton et al. is not adapted to select between an active measurement module and a passive measurement module. The Burton et al. reference also does not teach a control unit adapted to display the current level of brain function from only the selected module.

The Examiner states on page 6 of the Office Action that it is inherent that only one measurement can be taken at a time because if the patient is being stimulated, that is an active measurement, and if there is no stimulus, then that is an inactive measurement. The Examiner states that there is no way the two can be performed at the same time. The

applicant respectfully disagrees with the Examiner's conclusion and strongly asserts that this conclusion is technically inaccurate. Applicant admits that the system of Burton et al. teaches analysis using both EEG bispectral analysis (incorporating bi-coherence) and Audio Evoked Potential (AEP) analysis in an integrated fashion. However, both the EEG and AEP analyses are conducted at the same time. And contrary to the Examiner's assertion, it is not inherent that only one measurement can be taken at a time. Both EEG and AEP analyses can be taken simultaneously, even though the monitored result of an AEP analysis may be zero. Contrary to the system of Burton et al., the present invention is unique because it limits the amount of data and the physical structure necessary for retrieving such data to analyze the level of consciousness of a patient. For example, the sensor taught by Burton et al. requires both EEG and AEP sensors (see Figs. 36 and 37), whereas the present invention allows a unitary sensor having only one set of electrodes which are used intermittently for both passive and active measurements. This limits the amount of cost and time to produce and operate the system and also limits the amount of structure necessary for the sensing element to thereby limit mistakes made during medical procedures. The present invention also advantageously limits the space required on the display because data from only one of the active measurement module and passive measurement module is shown at a time.

In view of the comments provided above, claim 8 is neither anticipated nor rendered obvious by the Burton et al. reference.

Claims 9-11 And 13-16

Claims 9-11 and 13-16 depend directly or indirectly from claim 8 and thus are believed allowable for the reasons stated above, as well as the detailed subject matter recited therein.

Claim 12 is cancelled.

Claim 17

Claim 17 recites a system for monitoring the level of brain function in a patient. The system includes a control unit that is operable to select between the active measurement module and the passive measurement module such that the control unit

displays the current level of brain function from only one of the active measurement module and the passive measurement module at any given time. For the reasons stated above regarding claim 8, claim 17 is believed allowable over the applied references.

Claims 18-20

Claims 18-20 depend from claim 17 and thus believed allowable for the reasons stated above, as well as the subject matter recited therein.

Claim 21

Claim 21 is amended to more particularly point out and distinctly claim the subject matter of the present invention and render the same allowable over the applied references. More particularly, claim 21 is amended to include the step of positioning a unitary sensor on the patient, the unitary sensor being operable to detect the biopotential signals from the patient and deliver an auditory stimuli to the patient. As discussed above regarding claim 1, the Burton et al. reference fails to teach or suggest a unitary sensor that can detect biopotential signals and deliver an auditory stimuli to the patient.

Claim 21 is also amended to include means for combining the information from the active measurement module and the passive measurement module and the passive measurement module displays only a single depth of sedation based upon a selection between the passive measurement module and the active measurement module. As discussed above regarding claim 8, this aspect is neither taught nor suggested by the prior art.

Claim 21 is also amended to include the aspect that the unitary sensor includes a base strip including at least three electrodes to detect biopotential signals on the skin of the patient and an extension strip including an acoustic emitter operable to deliver the auditory stimuli to the patient. As discussed above regarding claim 1, Burton et al. fails to teach the recited unitary sensor including a base strip and extension strip and an acoustic emitter operable to deliver the auditory stimuli.

As such, claim 21 is believed allowable.

Application No. 10/667,237
Amendment Dated December 11, 2006
Reply to Office Action of August 10, 2006

Claims 22-28

Claims 22, 23, 25 and 26 depend directly or indirectly from claim 21 and are thus believed allowable for the reasons stated above as well as the detailed subject matter recited therein.

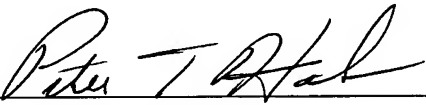
Claims 24, 27 and 28 are cancelled.

Conclusion

The present application is thus believed in condition for allowance. Such action is respectfully requested.

Respectfully submitted,

ANDRUS, SCEALES, STARKE & SAWALL, LLP

By 
Peter T. Holsen
Reg. No. 54,180

Andrus, Scales, Starke & Sawall, LLP
100 East Wisconsin Avenue, Suite 1100
Milwaukee, Wisconsin 53202
Telephone: (414) 271-7590
Facsimile: (414) 271-5770